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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/510,585 | 10/08/2004 | Debra L. Fleenor | 2354 US F | 1893 |

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Alcon Research
6201 South Freeway
Fort Worth, TX 76134-2099

| EXAMINER | |
|---|---|
| DAVIS, RUTH A | |
| **ART UNIT** | **PAPER NUMBER** |
| 1651 | |
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| 11/29/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/510,585 | FLEENOR ET AL. | |
| | Examiner | Art Unit | |
| | Ruth A. Davis | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's amendment and response filed on August 28, 2007 and the IDS filed on May 22, 2007 have been received and entered into the case. Claims 14 – 15 are added; claims 1 – 15 are pending and have been considered on the merits. All arguments have been fully considered.

### *Claim Rejections - 35 USC § 112*

Rejections under 35 U.S.C. 112, first paragraph, are withdrawn due to applicant's response.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 – 13 stand rejected under 35 U.S.C. 102(e) as being anticipated by Hellberg et al. (WO 03/027275).

Applicant claims a method for lowering intraocular pressure in a patient in need thereof, by administering a non-nucleotide/non-protein agents that inhibits expression of CTGF and a

pharmaceutical carrier. Administration is topical, intracamerall or via implant; in amounts of 0.01 – 2%; the patient suffers from glaucoma or ocular hypertension; the glaucoma is normal tension glaucoma. Applicant additionally claims the method for preventing visual field loss associated with POAG and compositions comprising the agent.

Hellberg teaches compositions comprising paullones and pharmaceutical carriers (p.4-5,10) in amounts of 0.01 – 5% (p.10-11) and methods for treating elevated intraocular pressure and glaucoma (p.4-5).

The reference anticipates the claimed subject matter.

3. Claims 1 – 15 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Pershadsingh et al. (US 6316465).

Applicant claims a method for lowering intraocular pressure in a patient in need thereof, by administering a non-nucleotide/non-protein agents that inhibits expression of CTGF and a pharmaceutical carrier. Administration is topical, intracamerall or via implant; in amounts of 0.01 – 2%; the patient suffers from glaucoma or ocular hypertension; the glaucoma is normal tension glaucoma. Applicant additionally claims the method for preventing visual field loss associated with POAG and compositions comprising the agent. The agent is selected from GW-8510, purvalanol A, roscovitine, troglitazone, ciglitazone, 15(S)HETE, and combinations thereof.

Pershadsingh teaches methods for treating glaucoma by administering PPARy agonists (col.2-3, 8, table 2) such as troglitazone or ciglitazone (col.13 line 20-30) and pharmaceutical

carriers, to the eye at 0.01 – 10% (col.14 line 29-35). Other routes of administration include topical (col.16), other conditions include prevent vision loss associated with POAG (table 2).

The reference anticipates the claimed subject matter.

4. Claims 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurtz et al. (US 5594015).

Applicant claims a composition for lowering IOP and providing neuroprotection in a patient in need thereof, the composition comprising at least one non-nucleotide/non-protein agents that inhibits expression of CTGF and a pharmaceutical carrier. The compounds is selected from GW-8510, purvalanol A, roscovitine, troglitazone, ciglitazone, 15(S)HETE, and combinations thereof.

Kurtz teaches compositions comprising ciglitazone or troglitazone and pharmaceutical carriers (claims).

Although the reference does not teach the claimed activity of the composition, the compositions are the same. Thus, the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112)

Therefore, the reference anticipates the claimed subject matter.

***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1 – 13 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 55 of copending Application No. 10/488,496.

Hellberg teaches compositions comprising paullones and pharmaceutical carriers (0012,0112) in amounts of 0.01 – 5% (0114) and methods for treating elevated intraocular pressure and glaucoma (0018-0019). Although the claims are not identical, the instant claims encompass those of the copending application.

This is a provisional obviousness-type double patenting rejection.

***Response to Arguments***

Applicant argues that the references do not teach all of the limitations of the invention. Specifically, in that they do not recognize classes of compounds that inhibit expression of CTGF which lower IOP. Applicant additionally states that a TD will be submitted upon allowance of the claims.

However, these arguments fail to persuade because the art clearly teaches compounds that lower IOP and treat glaucoma. While the references may not recognize that the broader class of compounds inhibits CTGF expression, they clearly teach the claimed methods of administering the claimed compounds to the eye for lowering IOP and treating glaucoma. Furthermore, it is noted that the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112)

Regarding the ODP, applicant's statements are acknowledged and made of record.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner
Art Unit 1651

November 19, 2007